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Original Article

Diffusion-weighted imaging and the Alberta Stroke Program Early CT Score (DWI-ASPECTS)-guided intra-arterial thrombectomy beyond 6 hours: feasibility, substantial efficacy, and acceptable safety

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Abstract: Objectives: To assess the safety and efficacy of intra-arterial thrombectomy for patients with acute ischemic stroke due to large vessel occlusion (LVO) treated beyond the traditional 6-hour window, using diffusion-weighted imaging and the Alberta Stroke Program Early CT Score (DWI-ASPECTS) for patient selection. Methods: A retrospective study was conducted at Hebei General Hospital, involving 263 acute stroke patients treated between November 2022 and August 2024. Patients were categorized into two cohorts based on treatment timing: within 6 hours (n = 156) and beyond 6 hours (n = 107). Outcomes included the modified Rankin Scale (mRS), National Institutes of Health Stroke Scale (NIHSS), degree of vascular recanalization (modified Thrombolysis in Cerebral Infarction [mTICI] scale), coagulation parameters, and adverse event rates as safety measures. Results: Demographics and baseline conditions were comparable across groups. The beyond-6-hour group showed prolonged time from symptom onset to intervention, with slightly higher mRS and NIHSS scores at discharge and 90 days, indicating poorer functional and neurological outcomes ($P < 0.05$ for both). The beyond-6-hour group had a significantly lower vascular recanalization rate (mTICI ≥ 2b: 84.11%) compared to the within-6-hour group (93.59%, $P = 0.013$). However, the overall safety profile was similar, with no significant differences in adverse event rates. Conclusion: Intra-arterial thrombectomy beyond the standard 6-hour window was feasible, showing substantial efficacy and an acceptable safety profile when guided by DWI-ASPECTS.

Keywords: Acute ischemic stroke, large vessel occlusion, thrombectomy, treatment window, DWI-ASPECTS, vascular recanalization

Introduction

Acute ischemic stroke, primarily caused by large vessel occlusion (LVO), is a leading cause of morbidity and mortality worldwide. Traditional management has focused on time-sensitive interventions, particularly intravenous thrombolysis within a limited window of up to 4.5 hours from symptom onset [1-3]. However, mechanical thrombectomy has revolutionized acute stroke care, significantly improving functional outcomes by retrieving thrombi causing occlusions in proximal cerebral arteries [4-6]. Thrombectomy has conventionally been recommended within a 6-hour window post-symptom onset, supported by pivotal trials demonstrating its benefits within this acute timeframe [7].

The introduction of advanced imaging techniques, notably diffusion-weighted imaging (DWI) and the Alberta Stroke Program Early CT Score (ASPECTS), has allowed for a more nuanced understanding of brain tissue at risk and the extent of salvageable penumbra, even beyond traditional time limits [8, 9]. This imaging-based approach challenges the conventional time-window limitations by offering an individualized assessment of cerebral viability, as evidenced by landmark trials such as DEFUSE 3 and DAWN [10, 11]. These studies extended the therapeu-

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tic window, supporting thrombectomy in selected cases up to 16 or 24 hours post-onset when guided by advanced imaging criteria, thus optimizing the retrieval of salvageable tissue [12].

Despite these advancements, thrombectomy beyond the 6-hour window remains underutilized in clinical practice due to concerns over safety and efficacy. Prolonged ischemia is often associated with complex thrombus morphology and the risk of reperfusion injury, presenting significant procedural and post-procedural challenges [10, 13, 14]. Therefore, robust evidence demonstrating comparable outcomes across extended timeframes is necessary to build clinician confidence in this innovative approach.

This study aimed to investigate the safety and efficacy of intra-arterial thrombectomy in patients with LVO strokes treated beyond the conventional 6-hour window, using DWI-ASPECTS to guide patient selection.

Materials and methods

Case selection

This retrospective study analyzed 263 patients with acute large vessel occlusive stroke who were admitted through the emergency neurology green channel at Hebei General Hospital between November 2022 and August 2024. The inclusion criteria were: patients aged 18 years or older with evidence of intracranial large artery occlusion confirmed by cerebral imaging techniques (computed tomography angiography [CTA], magnetic resonance angiography [MRA], or digital subtraction angiography [DSA]), who met the diagnostic criteria established by the American Heart Association/American Stroke Association (AHA/ASA) [15], had a National Institutes of Health Stroke Scale (NIHSS) score of 4 or higher [16], received endovascular reperfusion therapy, and had complete case and imaging data available.

Exclusion criteria included: patients with intracranial tumors, severe liver or kidney dysfunction, arteriovenous malformations, or other serious diseases; those who received only intravenous or intra-arterial thrombolysis; those with intracranial stenosis due to conditions such as vasculitis or cerebral vasospasm; patients with a recent intracranial hemorrhage or history of bleeding predisposition; individuals with contraindications to magnetic resonance imaging (MRI), including allergies to contrast agents, pregnancy, lactation, or the use of oral contraceptives; patients lost to follow-up or who died within 90 days post-treatment; individuals with prior strokes resulting in residual neurologic deficits affecting the neurological score; and patients with significant motion artifacts in imaging.

The patients were divided into two groups based on the time from symptom onset to femoral artery puncture (OTP): the within-time-window group, which included 156 patients treated within 6 hours, and the beyond-time-window group, which included 107 patients treated after this period. Patient demographics, intraoperative parameters, and postoperative adverse events were obtained from the hospital's case system.

This study was approved by the Institutional Review Board and Ethics Committee of Hebei General Hospital (No. 2024-351). Informed consent was waived, as the study was retrospective and used de-identified patient data, ensuring no risk to or effect on patient care. The waiver was granted in accordance with the ethical and regulatory standards governing retrospective research.

Data collection

Data on patient demographics, clinical characteristics, intraoperative parameters, and postoperative adverse events were obtained from the hospital's case system. Blood samples were collected before treatment and 90 days post-treatment to analyze coagulation parameters, including thrombin time (TT), prothrombin time (PT), and fibrinogen (FIB).

DWI-ASPECTS score: We assessed the extent of infarction using the ASPECTS based on diffusion-weighted imaging (DWI) from MRI scans performed at admission and at the 90-day follow-up. The MRI was conducted on either a 1.5 Tesla system (Signa; GE Healthcare) or a 3 Tesla system (Tim Trio; Siemens Medical Solutions). DWI was acquired with diffusion gradient b-values of 0 and 1000 s/mm^2. Imaging parameters included a repetition time (TR) of 3100 ms or 7000 ms, echo time (TE) of 111 ms or 80 ms, a field of view of 22 cm, a matrix size of

128 × 128, a slice thickness of 5 mm, an inter-slice gap of 1.5 mm, 18 slices, and a flip angle (FA) of 90°. ASPECTS was determined by evaluating ten regions in two slices within the middle cerebral artery territory:

The thalamic and striatal level, which includes M1, M2, M3, insula (I), lentiform nucleus (L), caudate nucleus (C), and posterior limb of the internal capsule (IC).

The level 2 cm above the thalamus, which includes M4, M5, and M6.

Each region was assigned 1 point, and the total score was calculated by subtracting the number of abnormal regions from 10. All imaging data were analyzed in a double-blind manner by two experienced neuroradiologists, with any discrepancies resolved by consensus.

Blood parameters: Blood samples were collected in the early morning before treatment and 90 days post-treatment, with 5 mL of fasting venous blood drawn from each patient. The blood was centrifuged at 3000 rpm for 10 minutes with a centrifuge radius of 15 cm. The serum was separated and stored at -80°C. Coagulation parameters, including TT, PT, and FIB, were measured using a coagulation analyzer (PUN-2048, Perlong Medical, Beijing, China).

Modified Rankin Scale (mRS): The functional status and quality of life of patients were evaluated using the mRS both before treatment and 90 days after treatment. The reliability of the mRS was supported by a weighted kappa of 0.93, with a 95% confidence interval of 0.85-1.00 [17]. The mRS consists of seven grades, ranging from 0 to 6, with higher scores indicating greater disability.

Efficacy evaluation: Clinical efficacy was evaluated at 90 days post-treatment based on changes in NIHSS scores from baseline. The NIHSS includes 11 items, each with specific scoring criteria, resulting in a total score from 0 to 42, with higher scores indicating more severe neurological deficits. The efficacy categories were as follows:

Essentially Cured: A reduction in NIHSS score of 91% to 100%.

Markedly Effective: A reduction in NIHSS score of 46% to 90%.

Effective: A reduction in NIHSS score of 18% to 45%.

Ineffective: A reduction in NIHSS score of 17% or less.

Worsened: An increase in NIHSS score of 18% or more.

The intraclass correlation coefficient (ICC) for NIHSS is 0.95 [16].

Vascular recanalization: At 90 days post-treatment, the degree of vascular recanalization was assessed using the modified Thrombolysis in Cerebral Infarction (mTICI) scale, with a kappa range of 0.632 to 0.82 [18]. The mTICI scale includes the following:

0 (No Perfusion): No reperfusion, indicating treatment failure.

1 (Penetration but No Perfusion): Very poor treatment effect with minimal reperfusion.

2a (Partial Perfusion): Partial reperfusion with incomplete blood flow recovery.

2b (Partial Perfusion): Partial reperfusion with better, but still incomplete, blood flow recovery.

3 (Complete Perfusion): Complete reperfusion, indicating a successful outcome.

Successful reperfusion was defined as achieving a mTICI score of 2b or 3.

Outcome measurement

The primary outcome measure was the degree of vascular recanalization, assessed using the mTICI scale. Secondary outcomes included functional independence (mRS score), neurological deficits (NIHSS score), safety (incidence of adverse events), and changes in coagulation parameters. The DWI-ASPECTS score was used to assess infarction spread at admission and 90-day follow-up.

Statistical analysis

Data analysis was performed using SPSS 29.0 (SPSS Inc., Chicago, IL, USA). Categorical variables are presented as [n (%)]. Chi-square tests were applied when the sample size was ≥ 40 and the expected frequency (T) ≥ 5. For T between 1 and 5, the corrected chi-square test was used. The Shapiro-Wilk test assessed the normality of continuous variables. Normally dis-

Table 1. Comparison of basic clinical information

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t/χ^2	P
Age	62.06 ± 6.27	61.86 ± 7.01	0.236	0.814
Sex (Male/Female)	108 (69.23%)/48 (30.77%)	73 (68.22%)/34 (31.78%)	0.03	0.863
Current or previous smoking	60 (38.46%)	39 (36.45%)	0.11	0.741
Current or previous drinking	31 (19.87%)	20 (18.69%)	0.057	0.812
ASPECTS	7.63 ± 0.36	7.67 ± 0.41	0.847	0.398
Medical history				
Atrial Fibrillation	6 (3.85%)	3 (2.8%)	0.012	0.911
Diabetes Mellitus	29 (18.59%)	19 (17.76%)	0.029	0.864
Previous stroke	12 (7.69%)	8 (7.48%)	0.004	0.948
Hypertension	85 (54.49%)	55 (51.4%)	0.243	0.622
TOAST classification			0.695	0.707
Large artery atherosclerosis	139 (89.1%)	92 (85.98%)		
Cardiogenic	3 (1.92%)	2 (1.87%)		
Other etiology or unknown etiology	14 (8.97%)	13 (12.15%)		
Occlusion site			0.32	0.997
ICA	53 (33.97%)	34 (31.78%)		
M1	20 (12.82%)	13 (12.15%)		
M2/3	9 (5.77%)	6 (5.61%)		
ACA	1 (0.64%)	1 (0.93%)		
PCA	9 (5.77%)	6 (5.61%)		
V-BA	64 (41.03%)	47 (43.93%)		
Anterior circulation	85 (54.49%)	54 (50.47%)	0.412	0.521
Family History of Stroke	21 (13.46%)	14 (13.08%)	0.008	0.929
Number of Thrombectomies			0.197	0.657
1	109 (69.87%)	72 (67.29%)		
≥ 2	47 (30.13%)	35 (32.71%)		

ASPECTS: Alberta Stroke Program Early CT Score; TOAST: Trial of Org 10172 in Acute Stroke Treatment; ICA: internal carotid artery; M1: middle cerebral artery M1 segment; M2/3: middle cerebral artery M2/3 segment; ACA: anterior cerebral artery; PCA: posterior cerebral artery; V-BA: vertebrobasilar artery.

tributed variables were expressed as mean ± SD and analyzed using a t-test with corrected variance. A two-tailed *P* value < 0.05 was considered significant.

Results

Comparison of demographic and baseline data

A total of 263 patients were included in the study, with 107 patients in the beyond-6-hour group and 156 patients in the within-6-hour group (**Table 1**). No significant differences were observed between the groups regarding age, gender distribution, smoking/drinking habits, DWI-ASPECTS scores, medical histories, Trial of Org 10172 in Acute Stroke Treatment (TOAST) classification, occlusion site, or thrombectomy procedures (all P > 0.05).

Comparison of treatment time

The time from symptom onset to imaging (OTI), time from symptom onset to femoral artery puncture (OTP), and time from symptom onset to reperfusion (OTR) were significantly longer in the beyond-6-hour group (all P < 0.001). However, the puncture-to-reperfusion time (PTP) was slightly shorter in this group (P = 0.004). Hospital stay duration did not differ significantly between the groups (P = 0.601) (**Figure 1**).

Comparison of coagulation indicators

Baseline coagulation profiles, including TT, PT, and FIB levels, were comparable between the groups (P = 0.788, P = 0.825, P = 0.797, respectively) (**Table 2**). At the 90-day follow-up, coagulation parameters remained consistent, with no

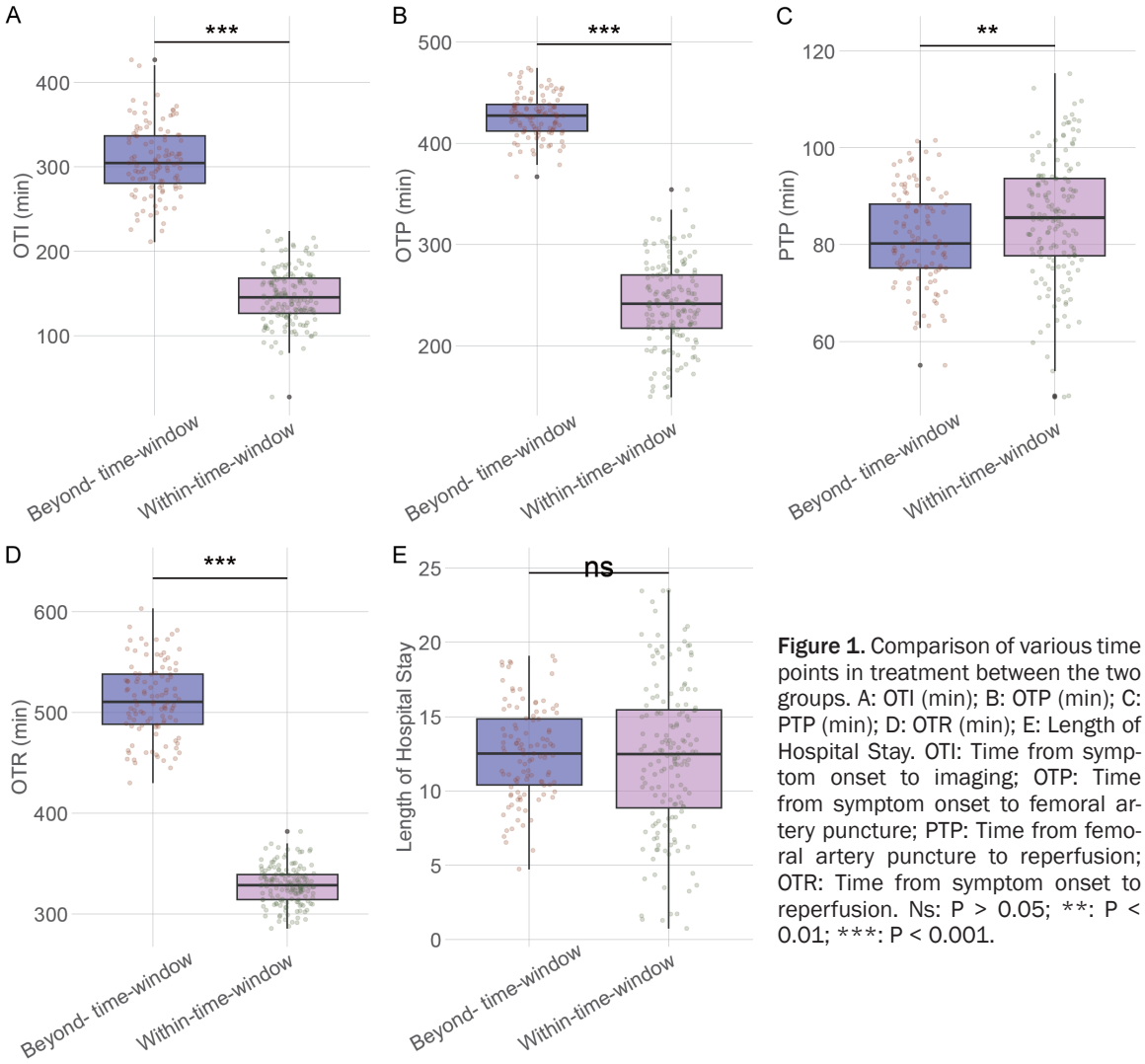

Figure 1. Comparison of various time points in treatment between the two groups. A: OTI (min); B: OTP (min); C: PTP (min); D: OTR (min); E: Length of Hospital Stay. OTI: Time from symptom onset to imaging; OTP: Time from symptom onset to femoral artery puncture; PTP: Time from femoral artery puncture to reperfusion; OTR: Time from symptom onset to reperfusion. Ns: P > 0.05; **: P < 0.01; ***: P < 0.001.

Table 2. Comparison of coagulation parameters before treatment between the two groups

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t	P
TT (s)	11.43 ± 1.62	11.48 ± 1.56	0.269	0.788
PT (s)	12.09 ± 1.23	12.13 ± 1.36	0.221	0.825
FIB (g/L)	3.91 ± 0.61	3.89 ± 0.64	0.258	0.797

TT: Thrombin Time; PT: Prothrombin Time; FIB: Fibrinogen.

Table 3. Comparison of coagulation parameters 90 days after treatment between the two groups

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t	P
TT (s)	13.58 ± 1.78	13.63 ± 1.85	0.214	0.831
PT (s)	13.49 ± 1.95	13.58 ± 1.81	0.39	0.697
FIB (g/L)	3.03 ± 0.26	2.97 ± 0.38	1.495	0.137

significant differences in TT, PT, or FIB levels between the groups (P = 0.831, P = 0.697, P = 0.137, respectively) (**Table 3**).

Comparison of mRS scores

At admission, mRS scores were similar between the groups (P = 0.741), indicating comparable baseline functional status. However, at discharge, the beyond-6-hour group exhibited significantly higher mRS scores (P = 0.029), reflecting slightly worse functional outcomes. This trend persisted at the 90-day follow-up, with the beyond-6-hour group maintaining higher mRS scores (P = 0.024) (**Figure 2**).

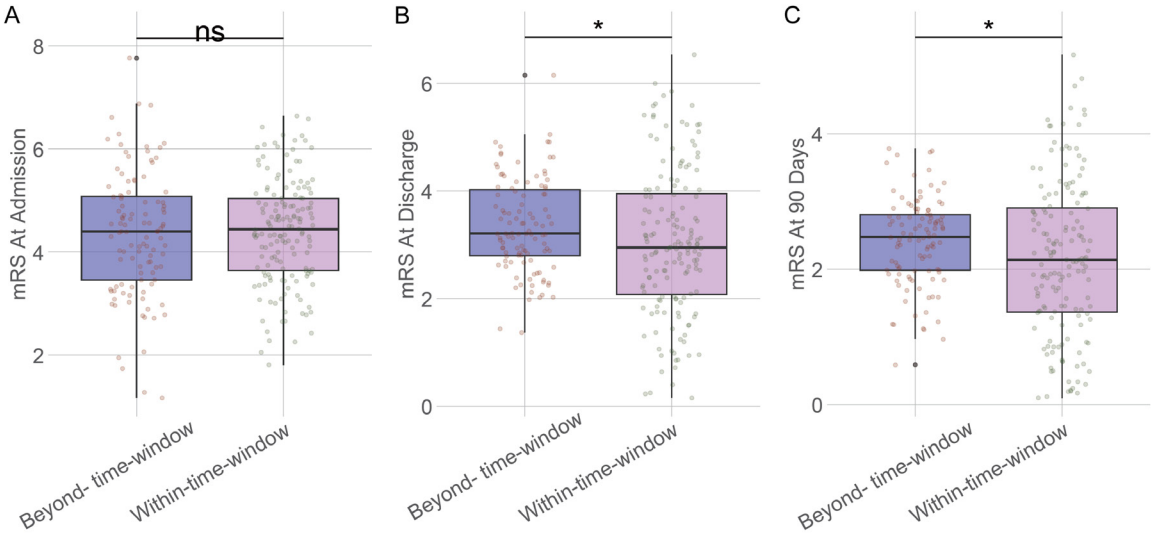

Figure 2. Comparison of mRS scores between the two groups. A: At Admission; B: At Discharge; C: At 90 Days. Ns: P > 0.05; *: P < 0.05.

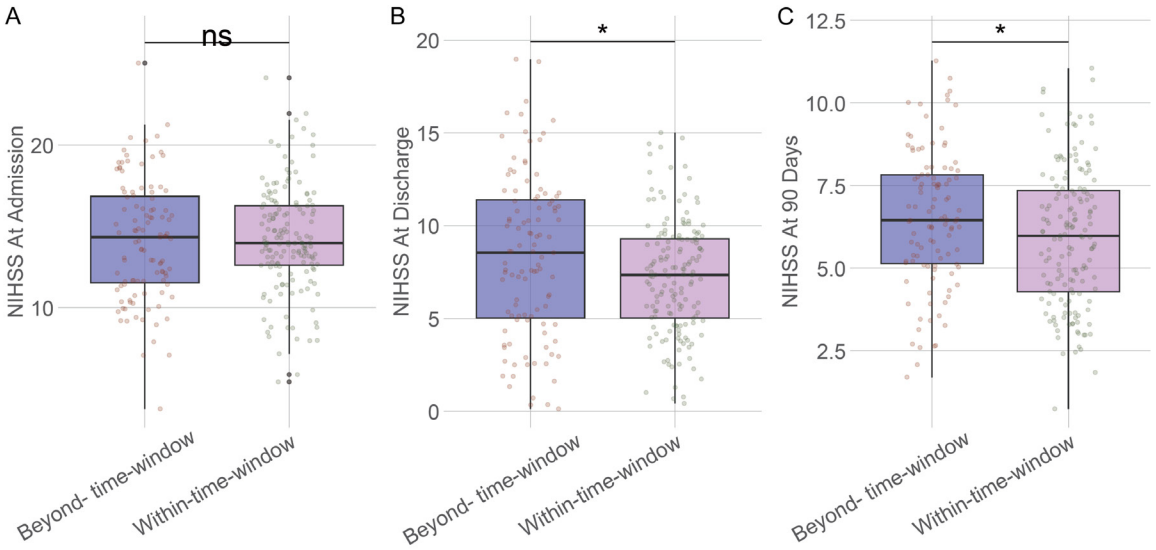

Figure 3. Comparison of NIHSS scores between the two groups. A: At Admission; B: At Discharge; C: At 90 Days. Ns: P > 0.05; *: P < 0.05.

Comparison of NIHSS scores

At admission, NIHSS scores were comparable between the groups (P = 0.891), indicating similar baseline neurological severity. By discharge, the beyond-6-hour group had significantly higher NIHSS scores (P = 0.025), reflecting poorer neurological outcomes. This difference persisted at the 90-day follow-up, with the beyond-6-hour group continuing to show higher NIHSS scores (P = 0.028) (**Figure 3**).

Comparison of effectiveness

The proportion of patients classified as essentially cured was similar between the groups, with 28.85% in the within-6-hour group and 25.23% in the beyond-6-hour group (P = 0.391) (**Table 4**). A markedly effective response was observed in 39.1% of the within-6-hour group compared to 36.45% in the beyond 6-hour group. In the effective response category, 23.08% of the within-time-window group and

Table 4. Comparison of therapeutic effect analysis between the two groups

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t	P
Essentially Cured	45 (28.85%)	27 (25.23%)	3.005	0.391
Markedly Effective	61 (39.1%)	39 (36.45%)		
Effective	36 (23.08%)	24 (22.43%)		
Ineffective	14 (8.97%)	17 (15.89%)		

Table 5. Comparison of mTICI grade between the two groups

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t	P
1 Grade	2 (1.28%)	4 (3.74%)	2.666	0.446
2a Grade	10 (6.41%)	10 (9.35%)		
2b Grade	75 (48.08%)	50 (46.73%)		
3 Grade	69 (44.23%)	43 (40.19%)		
Reperfusion Rate (%)	146 (93.59%)	90 (84.11%)	6.188	0.013

mTICI: modified Thrombolysis in Cerebral Infarction.

Table 6. Comparison of adverse event rates within 90 days between the two groups

Data	Within-6-hour (n = 156)	Beyond-6-hour (n = 107)	t	P
Asymptomatic Intracerebral Hemorrhage	3 (1.92%)	7 (6.54%)	2.547	0.111
Subarachnoid Hemorrhage	6 (3.85%)	7 (6.54%)	0.982	0.322
TIA Episode	4 (2.56%)	1 (0.93%)	0.241	0.623
Recurrent Ischemic Stroke	4 (2.56%)	4 (3.74%)	0.032	0.858
Postoperative Stent Occlusion	8 (5.13%)	6 (5.61%)	0.029	0.865

TIA: Transient Ischemic Attack.

22.43% of the beyond-6-hour group were classified. Conversely, the rate of ineffective outcomes was slightly higher in the beyond-6-hour group (15.89%) compared to the within-6-hour group (8.97%). While the proportions differed, these differences were not statistically significant, indicating comparable therapeutic effects across both patient cohorts.

Regarding reperfusion outcomes, 1.28% of patients in the within-6-hour group achieved a Grade 1 outcome, compared to 3.74% in the beyond-6-hour group (P = 0.446) (**Table 5**). Grade 2a outcomes occurred in 6.41% of the within-6-hour group and 9.35% of the beyond-6-hour group. Grade 2b outcomes were observed in 48.08% of the within-6-hour group and 46.73% in the beyond-6-hour group. Similarly, Grade 3 outcomes were achieved by 44.23% of the within-6-hour group and 40.19% of the beyond-6-hour group. The overall reperfusion rate was significantly higher in the within-6-hour group (93.59%) compared to the beyond-6-hour group (84.11%) (P = 0.013).

Comparison of safety

The incidence of asymptomatic intracerebral hemorrhage was 1.92% in the within-6-hour group compared to 6.54% in the beyond-6-hour group (P = 0.111) (**Table 6**). Subarachnoid hemorrhage rates were 3.85% and 6.54% for the two groups, respectively (P = 0.322). The incidence of transient ischemic attacks was low, with 2.56% in the within-6-hour group and 0.93% in the beyond-6-hour group (P = 0.623). Recurrent ischemic stroke occurred in 2.56% of the within-6-hour group versus 3.74% of the beyond-6-hour group (P = 0.858). Postoperative stent occlusion was observed in 5.13% of the within-6-hour group and 5.61% in the beyond-6-hour group (P = 0.865). Overall, the rates of adverse events were comparable between the two groups.

Discussion

This study examined the safety and efficacy of intra-arterial thrombectomy in patients with acute LVO strokes treated beyond the conven-

tional therapeutic time window, using DWI-ASPECTS scores as a guiding criterion.

A key finding of our study was that intra-arterial thrombectomy performed beyond the 6-hour window demonstrated comparable efficacy to treatment within the traditional time window. This supports the emerging view that mechanical thrombectomy can be safe and effective even when performed beyond the standard treatment window, provided that patient selection is rigorously guided by advanced imaging techniques, such as DWI-ASPECTS. DWI-ASPECTS, which assesses the extent of ischemic damage, played a crucial role in identifying patients likely to benefit from delayed intervention [19-21]. This approach aligns with recent trials, such as DAWN and DEFUSE 3, which advocate for the use of imaging to extend the treatment window for select patients, optimizing the retrieval of salvageable brain tissue [22-24].

Our findings suggest that using DWI-ASPECTS for patient selection allowed those with viable brain tissue, even beyond the conventional window, to achieve outcomes comparable to those treated within the recommended timeframe. A critical element of this approach was the identification of penumbral tissue that, although functionally compromised, remained perfused enough to sustain cellular integrity. This highlights the value of advanced imaging in acute stroke assessment, which, while complex, enhances patient evaluation and potentially increases the number of patients eligible for thrombectomy [25-27].

Post-treatment mRS and NIHSS scores revealed a subtle but consistent trend: patients treated within the traditional window had slightly better functional outcomes at discharge and at 90 days. These minor differences reflect the natural progression of ischemic injury over time and the potential for worsened outcomes with treatment delays. Cellular mechanisms such as excitotoxicity, inflammation, and blood-brain barrier disruption contribute to adverse changes in the ischemic core and surrounding penumbra. Thus, timely reperfusion is crucial to minimizing infarct growth and optimizing recovery [28-30].

However, it is important to recognize that secondary injury mechanisms continue to evolve beyond the acute phase. This underscores the value of addressing these pathophysiologic processes with adjunctive treatments after successful reperfusion [31, 32]. While our study did not investigate these interventions, they represent a promising area for future research to further improve outcomes in patients treated beyond conventional time windows.

Interestingly, the analysis of coagulation profiles both pre-treatment and 90 days post-treatment revealed no significant differences between the two groups. This indicates that coagulation status, a a key determinant of both initial thrombotic events and post-procedural complications, was consistent across the treatment timelines. This homogeneity can likely be attributed to stringent exclusion criteria, which effectively eliminated patients with severe coagulopathies [33, 34].

The rates of adverse events, such as asymptomatic intracerebral hemorrhage and subarachnoid hemorrhage, were comparable between the two groups, suggesting a consistent safety profile regardless of thrombectomy timing. This implies that, with careful patient selection and modern techniques, the risks associated with delayed thrombectomy may not be as significant as previously assumed. These findings may encourage the broader adoption of extended-window thrombectomy in clinical practice, potentially improving outcomes for a larger population of patients with LVO stroke.

A notable concern was the significantly lower vascular recanalization rate in patients treated beyond the 6-hour window, as reflected by the mTICI scores. Successful recanalization is critical to favorable clinical outcomes, and the observed disparity could stem from multiple factors. Delayed treatment, for example, often involves more organized and harder thrombi that are inherently more difficult to resolve [35-37]. Additionally, prolonged ischemia can lead to downstream microvascular occlusions and the no-reflow phenomenon, further hindering successful reperfusion [38].

Acknowledging these potential challenges underscores an essential point: while extended treatment windows offer lifesaving opportunities, they require refined techniques and possibly alternative or adjunctive strategies to

improve clot retrieval success. Future research should explore whether the adoption of new tools-such as more flexible or potent retrievers, aspiration devices, or pharmacological adjuncts-can address these difficulties and improve revascularization rates in patients treated beyond the conventional time window.

Finally, while this study contributes valuable insights to stroke management, several limitations warrant consideration. As a retrospective analysis, it may be subject to selection bias, and we could not control for all procedural variables. Therefore, prospective randomized trials specifically aimed at assessing thrombectomy efficacy beyond conventional windows in diverse populations are essential to substantiate our findings.

Furthermore, reliance on medical records for data collection may have missed important details related to the postoperative care and rehabilitation process, which could significantly affect long-term recovery but were beyond the scope of our analysis.

In conclusion, our results support intra-arterial thrombectomy as a viable treatment option for LVO stroke beyond the traditional time window, demonstrating substantial efficacy and an acceptable safety profile. However, optimal outcomes rely on a nuanced understanding of patient selection, pathophysiologic processes, and technical intricacies. The advancement of imaging technologies, coupled with ongoing innovations in thrombectomy techniques, holds promise for further extending treatment opportunities and improving outcomes for those affected by this debilitating condition. Continued research, particularly focusing on adjunctive therapies and strategies to address the unique challenges of delayed treatment, is crucial for advancing this important area of stroke care.

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Disclosure of conflict of interest

None.

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